Office of The Ombudsman, Hong Kong

Direct Investigation Report

Government's Mechanism for Monitoring Vaccines Provided by Private Healthcare Facilities

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www.ombudsman.hk.
English version of the report will be uploaded soon.

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Executive Summary
Direct Investigation Report

Government's Mechanism for Monitoring Vaccines Provided by Private Healthcare Facilities

Introduction

Advances in medicine have brought us more and more vaccines against diseases such as diphtheria, measles, pneumonia and influenza, etc. In recent years, a much talked-about vaccine is the human papillomavirus ("HPV") vaccine. In Hong Kong, some vaccines have been included in the Government's Vaccination Schemes and members of the public can receive scheduled vaccinations as they grow up. For vaccines not included in the Schemes, people can make their own arrangements according to their need and wish for vaccination.

2. Vaccines enter the human body through either injection or oral administration. Vaccines of defective quality would, therefore, directly affect or even jeopardise the health of those who are administered the products. Proper monitoring of vaccines by the Government is of paramount importance.

3. In mid-2019, there had been media reports that some private healthcare facilities ("PHFs") were suspected of providing defective nine-valent HPV vaccines. The Department of Health ("DH") and the Customs and Excise Department ("C&ED") subsequently took joint actions and uncovered counterfeit HPV vaccines in some PHFs. This had aroused public concern over the effectiveness of the Government's monitoring of vaccines.

4. This direct investigation, covering the Food and Health Bureau ("FHB"), DH and C&ED, aims at examining the Government's mechanism for monitoring vaccines provided by PHFs and exploring room for improvement, if any, as well as enhancing public understanding of the Government's monitoring efforts.

Our Findings

5. This Office has the following findings and comments with regard to the Government's mechanism for monitoring vaccines

provided by PHFs.

(I) Quite Comprehensive Monitoring Mechanism Already in Place for Vaccines Less Prone to Parallel Import or Counterfeit

6. For those vaccines that are in general less prone to parallel import or counterfeit, the Government has already put in place a quite comprehensive monitoring mechanism with gatekeeping measures at various levels to ensure the safety and quality of the vaccines. The measures include:

(1) the Pharmacy and Poisons Ordinance ("PPO") and the Pharmacy and Poisons Regulation ("PPR") stipulate that all vaccines must be registered with the Pharmacy and Poisons Board ("the Board") of Hong Kong before being sold or distributed in the territory. This is to ensure that all vaccines meet the prescribed criteria of safety, efficacy and quality;

(2) drug wholesale dealers must be holders of the licence issued by the Board and strictly observe the licencing conditions and the Code of Practice for Holders of Wholesale Dealer Licence to ensure proper handling of vaccines by the wholesale dealers;

(3) in Hong Kong, the import and export of vaccines are regulated by the Import and Export Ordinance ("IEO"). Licensed wholesale dealers must apply to DH for permits when importing/exporting vaccines and ensure that the vaccines match the descriptions in the permits. C&ED is responsible for enforcement actions such as post-shipment verification;

(4) DH monitors the vaccines available in the market in accordance with the PPO and PPR. It also handles complaints and joins forces with C&ED in enforcement operations according to the IEO and the Trade Descriptions Ordinance; and

(5) registered medical practitioners who breach the Code of Professional Conduct and provide unsafe or substandard vaccination service would face disciplinary actions by the Medical Council of Hong Kong.

(II) Inadequate Monitoring for Vaccines with Excessive

Demand in the Past

7. The 2019 incident involving the nine-valent HPV vaccines showed that the authorities' monitoring mechanism for vaccines with excessive demand had been inadequate in the past. The inadequacies, as we notice, fall mainly into three areas: (1) the risk assessment factors under DH's market surveillance mechanism do not include the pharmaceutical product's supply and demand in the market; (2) the laws executed by DH do not target counterfeit vaccines, and DH has no authority to conduct routine inspections at PHFs (including clinics of registered medical practitioners) solely on the ground of investigating counterfeit vaccines; and (3) education and publicity targeted at the main groups receiving the vaccination was insufficient and behind time.

8. Supply of the nine-valent HPV vaccines became tight since 2018. Around mid-2018, a lot of Mainland travellers complained that they could not get vaccinated at PHFs despite having made appointments in advance. DH, however, did not take immediate actions to strengthen monitoring of the nine-valent HPV vaccines provided by PHFs (such as requesting C&ED to conduct more post-shipment verifications on the imported vaccines, or keeping watch on advertisements targeting Mainland travellers who came to Hong Kong for vaccination so as to identify suspicious medical facilities or clinics), or step up publicity and education targeted at the groups taking the vaccination (Mainland travellers in particular). In addition, DH has no authority to conduct routine inspections at the PHFs involved solely for investigating counterfeit vaccines. Criminals then took advantage of the excessive demand in the market to provide parallel imported or counterfeit HPV vaccines.

(III) DH and C&ED Had Taken Prompt Actions in the Wake of the Incidents Involving Nine-Valent HPV Vaccines

9. When complaints involving nine-valent HPV vaccines started to rise significantly in May 2019, DH and C&ED immediately stepped up investigations against PHFs. Between May and September, DH conducted 24.8 investigations and took 20 joint actions with C&ED on average per month and succeeded in raiding several PHFs providing suspected counterfeit or parallel imported nine-valent HPV vaccines. Several people were arrested. Meanwhile, the two departments also implemented a number of strengthened monitoring measures, including conducting special inspections on those licensed wholesale dealers who had imported unregistered nine-valent HPV vaccines for the purpose of re-export; referring all import/export permits already issued involving

unregistered HPV vaccines to C&ED for post-shipment verification, and taking proactive investigations against suspicious PHFs. The number of complaints about nine-valent HPV vaccines plummeted since, and no further breaches of regulations have been found to date. Nevertheless, we must point out that the number of Mainland visitors to Hong Kong has dropped since mid-2019, and the number of people receiving nine-valent HPV vaccination in the territory has declined drastically since the third quarter of that year. The obvious decrease in related complaints during the period might be attributed to the prevailing circumstances, as much as to the actions taken by DH and C&ED.

(IV) The Government Failed to Explain in Detail to Public its Monitoring Mechanism and the Strengthened Monitoring Measures Introduced after the Incidents

10. In the wake of media reports in mid-2019 about PHFs providing allegedly defective nine-valent HPV vaccines, neither FHB nor DH took the initiative to explain in detail to the public the Government's monitoring mechanism for vaccines provided by PHFs or the strengthened monitoring measures introduced in response to those incidents. Although C&ED and DH had issued press releases with respect to the three operations between May and July 2019, they had only briefed the Legislative Council twice with regard to the strengthened monitoring measures newly introduced, and organised briefings for the licensed wholesale dealers directly affected. The general public had received very limited relevant information directly from the Government. Actually, people receiving the vaccination need to know how to protect their own welfare (for instance, by knowing how to find out if the vaccines have been registered and verify the authenticity of the vaccines). An informed and alert general public would also render the Government's monitoring and enforcement efforts much more effective. By announcing the results of this direct investigation, we hope to enhance public understanding of related information, and we urge FHB, DH and C&ED to learn from the experience to improve arrangements for information dissemination.

(V) When the COVID-19 Vaccines Become Available in the Local Private Market, Government Must Keep Relevant Information Accurate and Transparent and Ensure the Vaccines Meet Quality Criteria

11. COVID-19 affects all people in the world and there has been initial success in developing vaccines against it. Vaccination among the general population is expected to help relieve the epidemic.

Recently, some drug manufacturers are already mass-producing the vaccines, and many governments (including that of Hong Kong) have announced their own vaccination programmes. In the early days of rollout, demand for the vaccines will be huge across the globe and in Hong Kong. Information about the supply, safety, efficacy and test results of the vaccines may be quite confusing, or may even lead to misunderstanding and doubts of the general public. Furthermore, while Government-arranged vaccination programmes seem to be the main trend globally at present, it is still possible that drug manufacturers may supply the vaccines to the private markets in individual countries. When that happens, there may be legally imported and parallel imported vaccines, or even counterfeit vaccines in the local private market. FHB and DH must ensure transparency of information about the safety and efficacy of the vaccines, and about the arrangements of the Government's vaccination programme. Besides, they must strengthen the dissemination of accurate information to the public. Should the COVID-19 vaccines become available in the local private market, FHB, DH and C&ED must play the role of gatekeeper properly to ensure that the vaccines taken by members of the public at PHFs meet the quality criteria.

Our Recommendations

12. In the light of our findings and comments above, The Ombudsman makes the following recommendations to FHB, DH and C&ED:

(1) to keep a close watch on the effectiveness of the newly introduced strengthened monitoring measures, and make adjustments or amendments when necessary;

(2) to include the pharmaceutical product's supply and demand in the market as a risk assessment factor under DH's market surveillance mechanism;

(3) to review the information dissemination mechanism. Should serious incidents involving pharmaceutical products occur, they should promptly and proactively explain to the general public their monitoring mechanism, actions taken and the monitoring measures to be introduced so as to allay public doubts; and

(4) to enhance the transparency of information about vaccines newly introduced and proactively provide the public with information about the safety, efficacy and

supply of the new vaccines in a timely manner so that they can understand how to protect their health and welfare.

Office of The Ombudsman
March 2021

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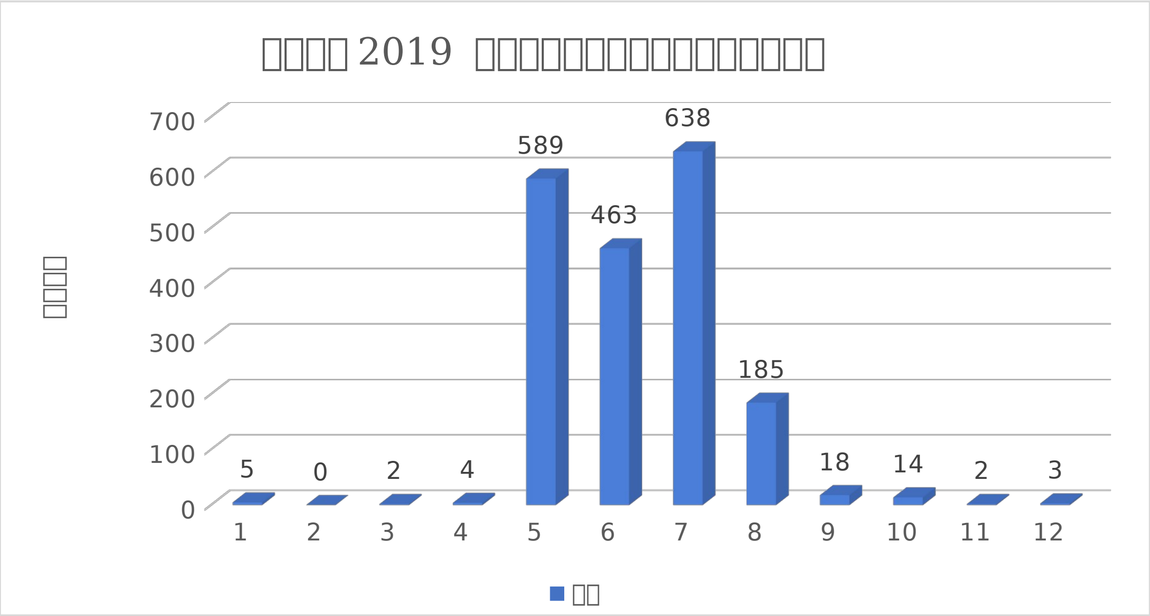

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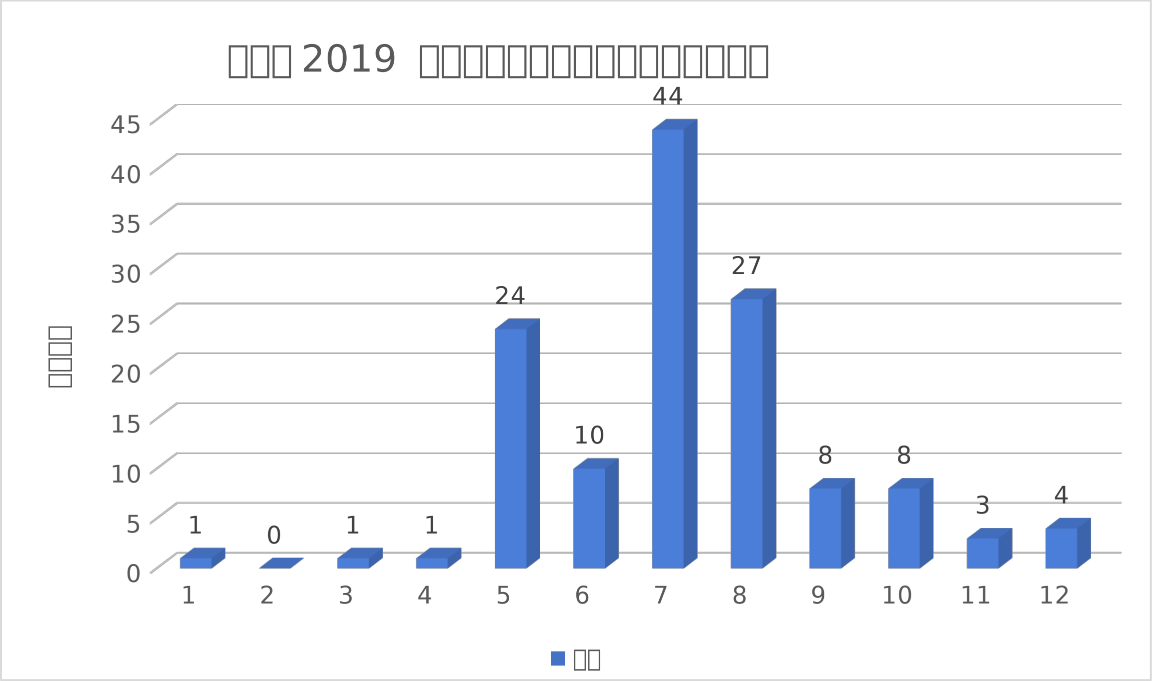

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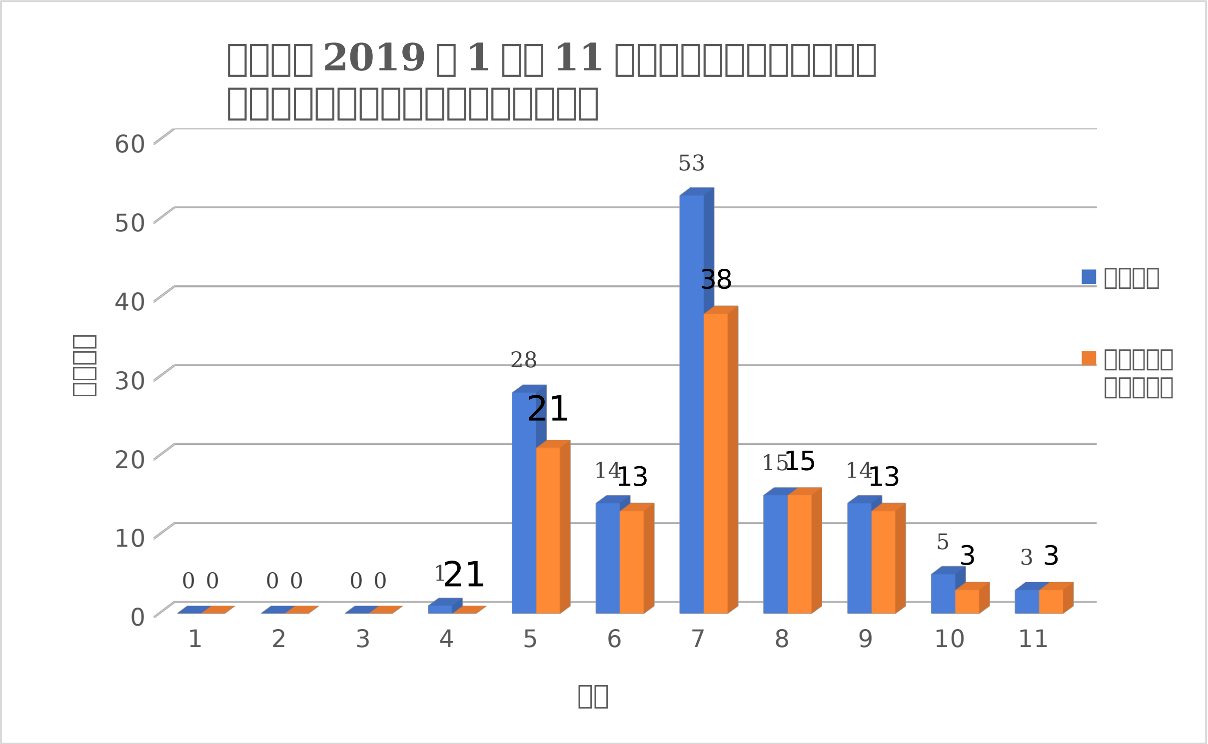

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3.14 □□
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3.15 □2019□7□10□□12□□□□□□□□□□□□□□□□□□□□□□□□□□
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4

[illegible]
[illegible]

[illegible]

4.1 [illegible] 2019 [illegible]

(1) [illegible]

(2) [illegible]

(3) [illegible]

4.2 [illegible]

(1) [illegible]

(2) [illegible]

(3) [illegible] 2020 [illegible]

[illegible]

4.3 [illegible]

4.4 [illegible]

(1) [illegible] 2019 [illegible] 5 [illegible]

[illegible]

[illegible]2019[illegible]25[illegible]3[illegible]

(2) [illegible]2019[illegible]5[illegible]**3**[illegible]**3.5**[illegible]**3**[illegible]

(3) [illegible] 2019[illegible]7[illegible]18[illegible]2019[illegible]8[illegible]2020[illegible]7[illegible]225[illegible]

(4) [illegible]2019[illegible]7[illegible]29[illegible]2019[illegible]8[illegible]2020[illegible]7[illegible]1[illegible]14[illegible]

(5) [illegible]2019[illegible]7[illegible]29[illegible]

(6) [illegible]2020[illegible]4[illegible]blockchain[illegible]eZTracker[illegible]

(7) [illegible]2019[illegible]5[illegible]30[illegible]

(8) [illegible]2019[illegible]**2.38**[illegible]**4**[illegible]

4.5 [illegible]
4.2 [illegible]

4.6 [illegible]

[illegible]

4.7 [illegible]

(1) [illegible] 2019 [illegible] 5 [illegible] 29 [illegible]

(2) [illegible] 2019 [illegible] 10 [illegible] 21 [illegible]

(3) [illegible] 2019 [illegible] 7 [illegible]

5

[illegible]

[illegible]

5.1 [illegible]

(1) [illegible] **2.1** [illegible] **2.3** [illegible]

(2) [illegible] **2.4** [illegible] **2.5** [illegible]

(3) [illegible] **2.7** [illegible] **2.9** [illegible]

(4) [illegible] **2.15** [illegible] **2.30** [illegible]

(5) [illegible] **2.34** [illegible]

5.2 [illegible] 2017 [illegible] 2018 [illegible] **2.9** [illegible] **2.16** [illegible] **2.22** [illegible] **2.5** [illegible] **2.9** [illegible] **2.21** [illegible] **2.26** [illegible] **2.35** [illegible] **2.36** [illegible] **3.2** [illegible] 2019 [illegible] (1) [illegible] **2.15** [illegible] (2) [illegible] **2.31** [illegible]; [illegible] (3) [illegible] 2018 [illegible]

5.3 □□□□□□□□□□□□□□□□□□□□□□2019□5□□□□□□□□□□□**3.3**□□**1**□□**3.4**□□**2**□□□□□□□□□□□□□□□□□□□□□□□□□**3.5**□□**3**□5□□9□□□□□□□□□□□□□24.8□□□□□□□□□□□□□20□□□**4.4**□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□

5.4 □□□□□□□□□□□□□□□□□□□□□□□□□□**3.3**□**4.1(1)**□□□□□□□□□2019□□2019□□3□□**5.3**□□□□□□□□□□□□□□□□

5.5 □□□2019□□□**2.33**□□2021□1□□

5.6 □□□□□□□□□2019□□

5.7 □□**4.3**□**4.4**□□□□□□□□□□□□□2019□5□□7□□3□□□□□□□□□□□□□□**3.8**□**3.10**□□**4.7**□□□**2.3**□□□□□□□□□□□□□□□□□□□□□□**4.4(6)**□□□

5.8 2019□□□

[illegible]2019[illegible]

[illegible]

5.9 [illegible]

(1) [illegible]**4.4**[illegible]**5.5**[illegible]

(2) [illegible]**5.2**[illegible]

(3) [illegible]**5.7**[illegible]

(4) [illegible]**5.8**[illegible]

[illegible]

5.10 [illegible]

[illegible]

5.11 [illegible]

[illegible]
[illegible]**OMB/DI/442**
2021[illegible]**3**[illegible]

公署會不時在面書上載個別投訴個案的調查報告，歡迎讚好或追蹤本署面書粉絲專頁，以獲取最新資訊：
https://www.facebook.com/Ombudsman.HK

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□□1

新聞公報

香港海關打擊非法進口藥劑製品

2019年6月5日

香港海關昨日（六月四日）拘捕一間體檢集團的兩名董事，他們涉嫌非法進口藥劑製品，違反《進出口條例》（《條例》）。

海關早前與相關部門進行聯合行動，搜查一間體檢集團分別位於油麻地及觀塘的兩間處所。經調查後，海關人員昨日拘捕一名六十一歲男子及一名四十四歲女子。

案件仍在調查中，被捕人士現正保釋候查。

根據《條例》，任何人士如非根據進口或出口許可證的規定而進出口任何藥劑製品，即屬違法，一經定罪，最高可被判罰款五十萬元及監禁兩年。

市民可致電海關二十四小時熱線2545 6182，或透過舉報罪案專用電郵帳戶（crimereport@customs.gov.hk）舉報違反《條例》事宜。

完

2019年6月5日（星期三）

□□2

2021/3/3

新聞公報

香港海關與衞生署採取聯合行動打擊冒牌疫苗（附圖）

2019年7月12日

香港海關與衞生署七月十日進行聯合行動，突擊搜查一所位於觀塘的醫務中心，檢獲約七十六盒懷疑冒牌疫苗及四十七盒含有第1部毒藥的疫苗，估計市值合共約二十八萬元。

衞生署早前接獲投訴，指有醫務中心使用懷疑有問題人類乳頭瘤病毒疫苗（又稱子宮頸癌疫苗），並可能涉及冒牌貨，因而轉介海關。海關在商標持有人協助下進行初步調查後，於七月十日與衞生署採取聯合執法行動，搜查一間位於觀塘區商業大廈內的醫務中心，檢獲該批懷疑冒牌及含有第1部毒藥的疫苗。

一名四十九歲的醫務中心男董事及一名三十三歲的男職員被捕。

海關及衞生署的調查工作仍在進行中。

海關版權及商標調查科高級監督關建強及衞生署總藥劑師陳詩濤今日（七月十二日）在記者會表示，海關及衞生署會繼續加強執法，遏止應用冒牌疫苗的活動。

海關提醒消費者應小心選擇信譽良好的醫務中心，如懷疑疫苗是冒牌貨，應先向有關商標持有人或其代理商查詢。同時，海關亦提醒醫務中心於採購疫苗時應小心謹慎，管有冒牌物品作任何商業用途屬嚴重罪行，須負上刑責。

衞生署呼籲市民若接種子宮頸癌疫苗後有不適，應尋求醫護人員的意見。根據世界衞生組織的建議，子宮頸癌疫苗接種的主要對象應為九至十四歲仍未性活躍的青少年女性。市民如有懷疑是否需要接種或補打相關疫苗，應諮詢醫護人員意見。此外，註冊醫護人員亦應只向持牌藥物批發商購買已註冊的藥劑製品。

根據《商品說明條例》，任何人銷售或為售賣用途而管有冒牌物品，即屬違法，一經定罪，最高可被判罰款五十萬元及監禁五年。

此外，根據《藥劑業及毒藥條例》，任何人未有按照條文的規定而管有毒藥表第1部所列任何毒藥，即屬違法，一經定罪，最高可被判罰款十萬元及監禁兩年。

香港海關與衞生署七月十日進行聯合行動，突擊搜查一所位於觀塘的醫務中心，檢獲約七十六盒懷疑冒牌疫苗及四十七盒含有第1部毒藥的疫苗，估計市值合共約二十八萬元。

香港海關與衞生署七月十日進行聯合行動，突擊搜查一所位於觀塘的醫務中心，檢獲約七十六盒懷疑冒牌疫苗及四十七盒含有第1部毒藥的疫苗，估計市值合共約二十八萬元。圖示懷疑冒牌疫苗（下）及正牌疫苗（上）包裝盒的分別。

完

2019年7月12日（星期五）

□□3

2021/3/3

新聞公報

香港海關與衞生署繼續採取聯合行動打擊冒牌疫苗（附圖）

2019年7月15日

香港海關與衞生署七月十二日進行聯合行動，突擊搜查一所位於尖沙咀的醫務中心，檢獲約一百六十二盒懷疑冒牌疫苗及一百六十三盒含有第1部毒藥的疫苗，估計市值合共約七十五萬元。

衞生署早前接獲投訴，指有醫務中心使用懷疑有問題人類乳頭瘤病毒疫苗（又稱子宮頸癌疫苗），於是與海關進行聯合調查。海關在商標持有人協助下進行初步調查後，於七月十二日與衞生署採取聯合執法行動，搜查一間位於尖沙咀區商業大廈內的醫務中心，檢獲該批懷疑冒牌及含有第1部毒藥的疫苗。樣本將盡快安排送往政府化驗所化驗。

一名三十五歲的醫務中心女董事及兩名分別二十七及三十歲的女職員被捕。

海關及衞生署的調查工作仍在進行中。

海關提醒消費者應小心選擇信譽良好的醫務中心，如懷疑疫苗是冒牌貨，應先向有關商標持有人或其代理商查詢。同時，海關亦提醒註冊醫護人員於採購疫苗時應小心謹慎，管有冒牌物品作任何商業用途屬嚴重罪行，須負上刑責。

衞生署呼籲市民若接種子宮頸癌疫苗後有不適，應尋求醫護人員的意見。根據世界衞生組織的建議，子宮頸癌疫苗接種的主要對象應為九至十四歲仍未性活躍的青少年女性。市民如有懷疑是否需要接種或補打相關疫苗，應諮詢醫護人員意見。此外，註冊醫護人員亦應只向持牌藥物批發商購買已註冊的藥劑製品。

根據《商品說明條例》，任何人銷售或為售賣用途而管有冒牌物品，即屬違法，一經定罪，最高可被判罰款五十萬元及監禁五年。

此外，根據《藥劑業及毒藥條例》，任何人未有按照條文的規定而管有毒藥表第1部所列任何毒藥，即屬違法，一經定罪，最高可被判罰款十萬元及監禁兩年。

香港海關與衞生署七月十二日進行聯合行動，突擊搜查一所位於尖沙咀的醫務中心，檢獲約一百六十二盒懷疑冒牌疫苗及一百六十三盒含有第1部毒藥的疫苗，估計市值合共約七十五萬元。圖示部分檢獲的懷疑冒牌疫苗及含有第1部毒藥的疫苗。

完

2019年7月15日（星期一）

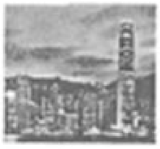
□□4

附件 4

精明消費香港遊

2020年10月19日 16:02 HKT 27 65%

消費者委員會 CONSUMER COUNCIL



涉及售賣偽冒藥物店舖資料（2020年2月至5月審理完結的案件）
涉及售賣偽冒藥物店舖資料（2019年12月和2020年1月審理完結的案件）
全城抗疫 個人家居衛生必讀貼士
涉及售賣偽冒藥物店舖資料（2019年9月和10月審理完結的案件）

最新報告

- 嬰兒奶粉價格表
- 最新15款嬰孩手推車測試
- 比較9款電子書閱讀器
- 測試26款無線頭戴式耳筒
- 測試20款嬰兒牙膠

焦點推介

- 涉及售賣偽冒藥物店舖資料（2020年2月至5月審理完結的案件
- 全城抗疫 個人家居衛生必讀貼士
- 涉及售賣偽冒藥物店舖資料（2018年4月審理完結的案件）
- 正版正貨
- 留意食肆「額外」收費

網站介紹 | 私隱政策 | 聲明和版權 | 相關網站 | 消費者委員會

新聞及資訊 > 健康及藥物教育 > 健康專題 > 疫苗接種
列印頁面

流動版本
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安全警示及藥物回收
給消費者的安全資訊
關於我們
新聞及資訊
相關網址
註冊藥劑製品（只提供英文版本）
持牌藥商（只提供英文版本）
香港持牌藥商搜尋
訂閱藥物新聞資訊

疫苗接種 ：正確時間、正確劑量，與合適的接種者

- 導言
- 疫苗的例子
- 接種安排（正確的時間）
- 正確的劑量
- 合適的接種者
- 疫苗常見的副作用
- 疫苗穩定性及其儲存條件
- 疫苗的相關規管
- 查證藥劑製品的註冊情況
- 提示如何區別產品是否有註冊
- 消費者的權益
- 總結

導言

現代的「疫苗」源於十八世紀的晚期。當時，一位顯赫的醫學家愛德華·詹納（Dr. Edward Jenner）引進突破性概念：採用已感染了「牛痘」的患者的膿液，用以預防一種致命的傳染病──「天花」（牛痘相對於天花是較為無害）。經實踐證明是安全有效。「疫苗」的英文字「vaccine」源於拉丁語「variolae vaccīnae（牛痘）」，就是個由來。

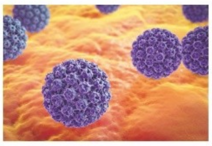
「疫苗」激活人們的免疫系統，防禦一些由病毒、細菌或其他致病原所引起的傳染病或癌症。疫苗是現代醫藥學成就的重要例子。世界衛生組織估計，疫苗在2010年至2015年期間，已於世界各地減少了因感染嚴重疾病而死亡的個案，至少有約一千萬宗。另外，疫苗亦已證實是能防禦，多種曾經肆虐，並且是致命的疾病（包括：天花、結核病、白喉、破傷風、百日咳等等）。

疫苗的例子

於香港常見的疫苗例子包括：

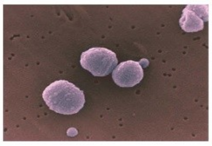
<u>預防病毒致病原</u>

- 甲型肝炎疫苗
- 乙型肝炎疫苗
- 人類乳頭瘤病毒（HPV）疫苗（或常稱「子宮頸癌疫苗」）
- 流行性乙型腦炎疫苗（或稱「日本腦炎（JE）疫苗」）
- 麻疹、流行性腮腺炎及風疹（MMR）混合疫苗（或稱「麻腮風聯合疫苗」；注：「風疹」又名德國麻疹German Measles）
- 輪狀病毒疫苗
- 季節性流感疫苗（或稱（「季節性流行性感冒疫苗」）
- 水痘疫苗



<u>預防細菌致病原</u>

- 卡介苗（BCG）
- 乙型流感嗜血桿菌（Hib）疫苗（或稱「b型流感嗜血桿菌疫苗」）
- 腦膜炎球菌疫苗
- 肺炎球菌疫苗



<u>綜合性疫苗</u>

- 白喉、破傷風、無細胞型百日咳及滅活小兒麻痺（DTaP-IPV）混合疫苗（註：「小兒麻痺症」的學名為：脊髓灰質炎）

▲ 返回最頂

接種安排（正確的時間）

疫苗能保護我們的身體，使身體產生免疫力；防禦可能遇到的真正的感染。從初生的階段開始，已可按既定的時間表接種疫苗。

例子包括：在香港兒童免疫接種計劃下，初生嬰兒會接種卡介苗，和第一劑乙型肝炎疫苗；滿1個月大的嬰兒，會接種第二劑的乙型肝炎疫苗。而白喉、破傷風、無細胞百日咳及滅活小兒麻痺症混合疫苗，則為已滿2個月、4個月和6個月的嬰兒按階段分別接種第一、第二及第三劑。

另外，年齡滿6個月的人（即：包括嬰兒、小童、青少年及成年人），可每年接種<u>季節性流感疫苗</u>。季節性流感疫苗須每年接種，是由於每年在社區裏流行的流感病毒種類都可能會轉變。建議大家安排於每年的流感季節前，至少兩個星期前的時間接種；因為我們的身體需要時間產生相關的抗體。

▲ 返回最頂

正確的劑量

一些疫苗只需要給予單一劑量，就可有終生保護。然而，大多數的疫苗都需要接種多於一次的劑量（即：相隔約數個月後接種第二劑，或第三劑）。有些疫苗，在上述的基礎療程的「多次劑量」後，更需要在某固定期限之後（如：一年或數年）接受「加強劑量」。個別的疫苗有不同的時間表；具體詳情可向醫護專業人士查詢。

疫苗普遍都是注射劑的形式；但也有其他劑型（例如：口服劑型和噴鼻劑型）。疫苗的劑量一般都很細小。注射劑（肌內或皮下注射）的份量通常約為0.5毫升；口服劑型的疫苗，則可高於1毫升；而噴鼻劑的份量，則是每個鼻孔約0.1毫升。個別的疫苗，會因應其特殊的用藥途徑和接種者的年齡而有所不同；例如：卡介苗用於初生嬰兒時，份量可低至0.05毫升皮內注射。從事醫護專業的人士，將根據產品說明，給予個別年齡組別的人適當的建議劑量。

要注意，必須完成疫苗的整個療程。如果錯過了其中任何一劑，應該儘快看醫生並諮詢其專業意見。

合適的接種者

不同的疫苗產品都有其特定適應症和目標群。例如：人類乳頭瘤病毒疫苗，是預防因持續感染人類乳頭瘤病毒而引致的子宮頸、外陰、陰道和肛門的病變與癌症。年滿9歲的人士，已可接種人類乳頭瘤病毒的疫苗。

另外，以季節性流感疫苗為例，滿6個月大的嬰兒已可接種流感疫苗；長者、小童、孕婦、長期病患者（如心、肺、腎有病的，代謝性疾病和免疫功能不全者）和肥胖人士（體重指數（BMI）數值30或以上），有較高風險感染流感和受其併發症影響的，亦特別鼓勵接種，以給予個人保護。居於安老院舍或殘疾院舍的院友亦有需要接種。除此之外，醫護人員、從事家禽業、養豬業的人員和其他有較高風險感染流感的人士，也應接種流感疫苗，以保障其個人健康。

符合接種疫苗的，應及時並按照時間表接種。在香港兒童免疫接種計劃下，兒童將按照建議的時間表於不同年齡接種相關的疫苗。至於要離境外出到高風險地區，需要接種疫苗提供預先保護的外遊人士，在計劃行程前，可先瀏覽旅遊健康服務的網頁。

並不是每個人都適合每一種疫苗。接種人士要經註冊醫生評估後才可接種。某些人（雖然較為罕見）會對個別疫苗有過敏反應（如蕁麻疹，和喘鳴症狀等）；這些人士將不適合接種該等疫苗。

醫護人員會詢問接種者的病史，及有沒有對疫苗曾有過敏反應；並評估其身體狀況，以決定應否給予疫苗，或繼續接種。

▲ 返回最頂

疫苗常見的副作用

疫苗能激發免疫反應，也有機會引發副作用。在接種後，醫護人員會建議接種者逗留觀察一段時間（例如：十五分鐘至半個小時）；這樣，倘若有急性的過敏發生，也可及時治理。

一般來說，疫苗的副作用都是輕微和短暫的，並且會在數天內消退。常見的副作用包括：注射部位出現疼痛（有時會發紅、腫脹和變硬）。接種者也可能感到疲倦，或肌肉疼痛。有些人可能會發燒、頭痛等等。口服疫苗可能會引起腸胃不適（如腹瀉）。每種疫苗的副作用都有所不同。若數天後仍然持續，或甚至惡化，則應向醫生求診。

如遇有嚴重的不良反應（例如：口腔和舌頭腫脹、呼吸困難或麻痹）須立即求醫。

整體來說，疫苗是安全的；它們在推出市場之前，已確立其效能和品質的要求。

關於兒童免疫接種的資訊，您也可瀏覽衞生署的家庭健康服務網頁；如要知道更多關於傳染病的資訊，您亦可查看衞生防護中心網站。

疫苗穩定性及其儲存條件

疫苗應按製造商建議的條件下儲存。每種疫苗有其個別的使用限期和儲存條件，並且會在標籤上列明。一般而言，疫苗須儲存於攝氏2度至8度之間，並且避免光線照射。應對儲存條件（如：溫度）進行密切監測及記錄。如果疫苗在建議環境以外的情況下儲存，則會影響其品質和效能；可能引致疫苗不能使用。雖則疫苗普遍應儲存於攝氏2度至8度之間，但是在接種前，疫苗可於室溫保存一段短時間。

大多數的疫苗都不應冷凍（不可於冰點以下），如果疫苗未有依指示儲存而曾結冰，則須棄置。

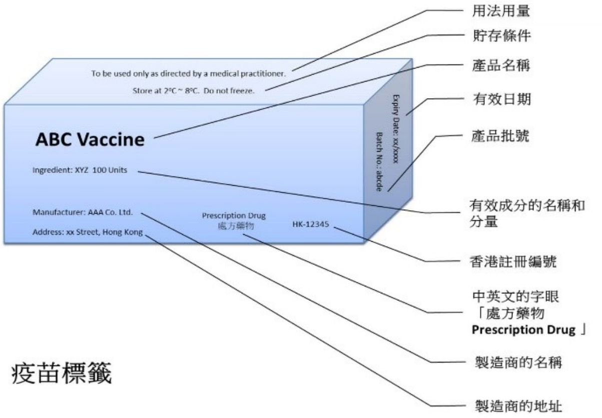
疫苗在應用前，應檢查其外觀是否有異常情況，或疫苗內有否異物。如有懷疑，都不應使用。

▲ 返回最頂

疫苗的相關規管

疫苗屬處方藥物（即：須經註冊醫生處方）；及與其他的藥劑製品一樣，必須經「香港藥劑業及毒藥管理局」註冊，才可在香港銷售或分發。藥劑製品的進/出口商必須持有根據「藥劑業及毒藥條例（第138章）」發出的批發商牌照，並須就每次裝運的貨物申請進/出口許可證。

於所有的註冊藥劑製品的最外層包裝（標籤）上，必須有香港註冊編號（即HK-XXXXX（五位數字））。除此之外，標籤須有產品名稱、有效成分的名稱和份量、製造商的名稱和地址、批次編號和使用限期。而所有的處方藥物，亦須標示有「處方藥物Prescription Drug」的中英文字眼（圖）。



疫苗標籤

無菌製劑的內包裝（即：疫苗的小瓶或注射管）的標籤上，亦應印有批次編號和使用限期；及如含有防腐劑的話，則須包括其名稱。

疫苗的特殊儲存要求（例如：須儲存於2°C ~ 8°C；不可冷凍），亦須清晰列載於標籤上。

▲ 返回最頂

查證藥劑製品的註冊情況

註冊藥劑製品資藥物料，可查看藥物辦公室的網站（http://www.drugoffice.gov.hk）：

(1) 於「香港註冊藥劑製品搜尋」功能，可輸入一些文字（如：產品或有效成分的英文名稱，或香港註冊編號）以搜尋藥劑製品的相關細節。
https://www.drugoffice.gov.hk/eps/do/tc/consumer/search_drug_database.html

(2) 於「藥劑製品目錄」的網上連結，以英文順序的方式查看藥劑製品的有關資料。
https://www.drugoffice.gov.hk/eps/do/tc/doc/Compdium.pdf.

提示如何區別產品是否有註冊

如上所述，疫苗的包裝盒或標籤上，會印有香港註冊編號，和「處方藥物Prescription Drug」的字眼。如果在疫苗的外盒上未能找出這些資料，則該產品有可能沒有在香港註冊。

根據現行法例，藥劑製品的名稱及其有效成分，是以英文註冊；所以產品的外盒都會有英文的「產品名稱」和「有效成分」名稱；有些產品除了有英文的產品名稱之外，還有中文的產品名稱。而其他的資料（如：使用說明、警告字句）則會以中文及 / 或英文顯示。間中在標籤上，除了中文與英文外，您可能會看到第三種語言（例如：一些也會運到其他歐洲國家的產品，也會有歐洲語文的字體）。然而，如果您注意到疫苗的外盒「只」有外國的語文，或「只」有中文（簡體字或繁體字），則該產品很可能是沒有在香港註冊。一些例子包括：外盒僅有日文；或該產品僅印上簡體或繁體的中文，而沒有英文的產品名稱。

消費者的權益

疫苗屬處方藥物，消費者通常會到註冊醫生執業的處所(如:醫院、診療所、其私人診症室)接種疫苗。接種疫苗時需要由註冊醫生及在其監管下進行。消費者在接種疫苗前，可先查看負責人是否為香港註冊的醫生。您可在「香港醫務委員會」的網頁內尋找註冊醫生名單的相關資料 https://www.mchk.org.hk/tc_chi/list_register/index.html。

在有需要的情況下, 市民可要求提供接種服務的醫護人員給予相關疫苗作檢視，並核對疫苗產品標籤上的「藥物註冊編號（HK-XXXXX）」的五位數字，以及查看產品的最外層包裝上有沒有所需的必要資料。如懷疑產品沒有在香港註冊，可向衞生署的「藥物辦公室」查詢或提出舉報（電話：+825-2572-2068；電郵：pharmgeneral@dh.gov.hk）。

關於如何辨別產品的真偽，您可聯絡個別產品註冊證明書的持有人。消費者可先對照產品的防偽特徵，及核對批次編號及使用限期等資料。如有懷疑的個案，可聯繫「香港科研製藥聯會」及查詢 (電話：+852-2528-3061；電郵：info@hkapi.hk）。若要對偽冒產品提出舉報，可直接與「香港海關」聯絡（電話：+852-2815-7711；電郵：customsenquiry@customs.gov.hk）。

▲ 返回最頂

總結

疫苗的品質有嚴格監控；儲存及運輸過程亦有特別要求。疫苗是處方藥；雖然可能有副作用，但卻有助於我們產生免疫能力，對抗致病原。能對疫苗多一點認識，及適當的使用；疫苗是能好好的保障我們大眾市民的健康。

▲ 返回最頂

鳴謝：藥物辦公室特此致謝「衞生防護中心」對撰寫本文給予的寶貴意見。

衞生署藥物辦公室
2019年12月